STA OP! Managing pain and challenging behaviour in nursing home residents with dementia

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Summary and General Discussion

The overall aim of the work in this thesis was to investigate the implementation and effectiveness of the stepwise, multidisciplinary and multicomponent intervention for pain and challenging behaviour in dementia, the STA OP! (acronym for the adapted and translated version of the STI).[1]
In this final chapter, the main results are summarised and discussed. In addition, methodological considerations are addressed, implications for clinical practice and policy are presented, and some recommendations are made for future research.

Summary of the main findings

CH 2 What is the current state-of-the-art with respect to challenges related to pain management in dementia?

In ***Chapter 2*** we present the results of a literature review on the current state-of-the-art with respect to challenges related to pain management in dementia. The evidence emerging from this review reveals the lack of effective assessment and treatment of pain across the range of clinical dementia settings. Pain is common among older people due to the increased prevalence of age-related diseases such as osteoporosis, arthritis and cardiovascular diseases. Although this also applies to people with dementia, individuals with dementia appear to experience the intensity and affective component of pain differently from their cognitively intact counterparts. In addition, a decline in communication capacity often leads to serious difficulties for healthcare professionals in their aim to detect pain, particularly in the more severe stages of dementia. Dementia limits the subjective reporting of pain that would normally be expected with cognitively healthy adults and, as a result, important information becomes inaccessible for care professionals.

In people with dementia, pain is often expressed in the form of specific neuropsychiatric behaviours, such as verbalisations/vocalisations (e.g. calling out), facial expressions (e.g. grimacing), restless or strained body expressions (e.g. increased pacing/rocking), agitation/aggressiveness, and resistance to care. These behaviours are often challenging for relatives and healthcare professionals, and are frequently interpreted as a symptom of the dementia. However, in many cases they are also the most prominent, or even the only feature of pain[2-6], but are not recognised as such.

The challenges inherent in the assessment of pain in people with dementia can lead to healthcare professionals being insufficiently prepared to handle the difficulties in establishing good pain management practice for these patients. The literature suggests that a large proportion of these issues might be overcome through better education for professionals on specific aspects of pain

management, and through more effective facilitation of pain assessment within organisations.

CH 3 What is the current state of evidence regarding the effectiveness of interventions targeting behaviour on the outcome 'pain', and interventions targeting pain on the outcome 'behaviour', in dementia?

There is an increasing evidence that psychosocial and behavioural interventions are effective in reducing challenging behaviours.[7-12] However, the connection with pain (as a cause of underlying pain or distress) has been made by very few studies and little is known about the influence of these behavioural interventions on pain. Despite that it remains unclear how pain and challenging behaviour co-occur, it is established that they are correlated.[13,14]

Although research on the *'recognition of pain in dementia'* has received more attention, it is still not clear which interventions are effective in reducing pain and behavioural symptoms in dementia at the same time. Therefore, to acknowledge the complexity of the relation between pain and behaviour in dementia, and also to investigate which interventions are effective in reducing pain and behavioural symptoms in dementia, we conducted a systematic literature review.

Chapter 3 presents the comprehensive review and describes the current evidence for the effectiveness of interventions targeting pain, behaviour (or both) in dementia. We systematically searched the literature for evidence, using a broad search strategy. After analysis of 893 potentially relevant hits, sixteen publications were finally included that described the effects of interventions targeting pain or behaviour in people with dementia. Of these, six publications focused on a pain intervention targeting behaviour, one focused on a behavioural intervention targeting pain, and nine focused on an intervention targeting both pain and behaviour.

Evidence from the reviewed publications suggests that pain interventions targeting behavioural disturbances, and behavioural interventions targeting pain, are effective in reducing both pain and behavioural symptoms in dementia. The evidence emerging from the review supports the idea that better pain assessment and management, preferably individually tailored, may also be an effective strategy in managing challenging behaviour. Also, because behavioural symptoms may arise from a variety of physical or psychological needs, an approach targeting both pain and behaviour is recommended. However, most of the interventions in the included studies were only examined once and had moderate methodological quality. Nevertheless, the findings do point in the same direction, i.e. large-scale research on these complex interventions, as well as the replication of their results, are warranted.

CH 4 One of the few interventions that acknowledged the complex relation between pain and challenging behaviour, and also proved effective in reducing discomfort and challenging behaviour, was the Serial Trial Intervention (STI)[15], developed by Christine Kovach in the USA. We translated and adapted this intervention to the Dutch healthcare setting. ***Chapter 4*** presents the protocol of the cluster randomised controlled trial (RCT) that investigated the effectiveness of implementation of the adapted/translated version of the STI (called STA OP! in the Netherlands).[16] Before starting the cluster RCT, a pilot study was conducted to test the feasibility and content of the materials, the multidisciplinary team training, as well as the time required to assess the primary and secondary outcome measures, performed by a trained research assistant and a nursing staff member (a certified nursing assistant or a registered nurse).[17] This pilot study indicated that STA OP! and the measurements were feasible and that no significant adjustments to the content, the materials or the training material needed to be made.

CH 5 ***Does implementation of STA OP! lead to a reduction of pain and improvement of pain management in residents with advanced dementia?*** ***Chapter 5*** describes the effects of implementation of STA OP! on pain and pain medication. In a cluster RCT, 21 psychogeriatric units in 12 nursing homes (covering 288 residents with advanced dementia) were included in the STA OP! study; i.e. 11 units covering 148 residents in the intervention condition, and 10 units covering 140 residents in the control condition. Staff working on the intervention units received the comprehensive stepwise multidisciplinary and multicomponent team training. Staff working on the control units received training on general nursing skills, dementia management and pain but, importantly, this training did not include the stepwise component.

Symptoms of pain and/or pain-related behaviour were recorded using the Dutch version of the Pain Assessment Checklist for Seniors Limited Ability to Communicate (the PACSLAC-D)[18] and the pain scale of the Minimum Data Set-Residents Assessment Instrument (the MDS-RAI pain scale)[19], the primary outcomes for pain as per protocol.[16] The PACSLAC-D is a structured observational pain assessment instrument with 24 items and was selected because it is one of the most feasible of the available valid pain observation scales in the Netherlands.[20] The MDS-RAI pain scale reflects a caregiver's evaluation based on observations, patient files and experiences in patient contact during the previous 7 days. Use of pain medication was recorded and retrieved from medication lists and then classified using the Anatomical Therapeutical Chemical classification (ATC).[21]

Logistic Generalized Estimating Equations (GEE) analyses showed that, during

the RCT, residents in the intervention condition compared to the control condition were significantly more likely to receive opioids, but not paracetamol or other analgesics. Multilevel modelling showed an overall significant effect of the intervention on observed pain, as measured with the PACSLAC-D, but not on estimated pain (the MDS-RAI pain scale). Additionally, we found that, at baseline, nursing staff estimated a considerably lower prevalence of pain as assessed with the MDS-RAI pain scale (estimation of pain) compared with an observation of pain as assessed with the PACSLAC-D.

CH 6 Does implementation of STA OP! lead to fewer expressions of challenging behaviour, better mood, and less use of antipsychotics in residents with advanced dementia?

In ***Chapter 6*** we describe the effects of implementation of STA OP! (as measured in the cluster RCT) on challenging behaviour, mood, and psychotropic medication. The primary outcomes for challenging behaviour were agitation (the Cohen-Mansfield agitation inventory, CMAI) and neuropsychiatric symptoms (the Neuropsychiatric Inventory-Nursing Home version, NPI-NH). Secondary outcomes included the use of psychotropic medication and symptoms of depression (the Cornell Scale for Depression in Dementia, CSDD; the Minimum Data Set-Depression Rating Scale, MDS-DRS).

Multilevel modelling showed an overall effect of the intervention on challenging behaviour and depression; scores on the CMAI, NPI-NH, CSDD and MDS-DRS were significantly lower in the intervention condition compared with the control condition. Logistic GEE analyses showed that residents in the intervention condition, compared to the control condition, were significantly more likely to receive antidepressants, but not antipsychotics, anxiolytics, and hypnotics/sedatives.

We conclude that implementation of STA OP! led to a significant and clinically relevant decrease in challenging behaviour and depression in nursing home residents with dementia. Importantly, these effects were achieved with no increase in the use of psychotropic drugs.

CH 7 With regard to the implementation process of the STA OP!:

- ***What are the experiences of healthcare professionals with implementation of STA OP! and its actual use in daily practice?***
- ***Is STA OP! delivered and implemented as intended at the level of the team and of the individual resident/professional?***
- ***What facilitating or impeding factors are associated with implementation at the level of the organisation, the team, or the individual resident/professional?***

Care innovations do not automatically find their way into practice, even if the staff is motivated to use them. Generally, this requires an active approach and an implementation plan with effective strategies.[22,23] In our RCT, an implementation strategy combining several components was pre-defined.[16] Prior to, during and after implementation of the STA OP! various activities (i.e. formation of promotion groups, performing site visits, providing feedback, and answering questions on pain or affective discomfort) were planned to promote use of the STA OP! in daily practice.

Chapter 7 describes a process evaluation of the *implementation* of the STA OP! using a mixed-methods design encompassing various data sources. In this process evaluation, the inhibiting and facilitating factors were described according to the 1) *organisational* level, 2) the *team* level, and 3) the *individual resident/professional* level. Quantitative data (i.e. from the written evaluations of healthcare professionals, management, and the research database) were analysed using descriptive statistics. Qualitative data (i.e. semi-structured interviews, notes, completed intervention forms, and written evaluations) were analysed according to the principles of thematic analysis.

Analysis of the data showed that the training, the steps of the intervention, the manual and the forms used, were found to be very informative, relevant and feasible. In the multidisciplinary team training (five sessions of 3-hours each) healthcare professionals were trained in the stepwise working method of the protocol, and in enhanced physical and affective assessment skills that target unmet needs commonly found in individuals with advanced dementia. Professionals indicated that the training was intensive. However, written evaluations indicate that, of the 136 participants, only 29.4% found the meetings to be too long, and 12.5% indicated that they contained too much information.

Factors *inhibiting* the implementation process at the 1) *organisational* level concerned instability of the organisation and the team, e.g. involvement in multiple projects/new innovations, staff turnover/absence of essential disciplines, and/or high workload. Factors *facilitating* implementation at the 2) *team* level were the presence of a person with a motivational leadership style, interdisciplinary

cooperation in the multidisciplinary training, securing the intervention by use of clear agreements, and written reporting or transfers; and at the 3) *individual resident/professional* level these factors were the perceived value of the stepwise working method, and enhanced awareness.

Although the process evaluation shows that STA OP! was not implemented on all units and was not always used as planned, the nursing home staff felt 'empowered' in their daily care of the target group. In addition, they experienced an increased awareness of the signals of pain and challenging behaviour.

Methodological considerations

This section addresses the methodological considerations regarding interpretation of the results of the STA OP! trial.

Cluster-randomised design

Implementation of the STA OP! is an example of a complex intervention as it contains several interacting components, such as training/education of the staff, and multidisciplinary involvement. Since the training/education of staff was at the team level (i.e. a multidisciplinary team was trained in the stepwise working method) a cluster, rather than an individually randomised design, was chosen.

Contamination, selection and allocation bias

Use of a cluster-randomised design, instead of an individually randomised design, implies that the risk of contamination bias by the staff was minimised. In addition, to avoid selection and allocation bias, nursing homes (i.e. clusters) and eligible residents were identified before allocation. After consent was obtained, an independent researcher (unaware of the trial conditions) performed the randomisation.

Nursing homes were randomly assigned to either the intervention condition (implementation of the STA OP!) or to the control condition (general training without the stepwise approach). In order of registration, a separate number was assigned to every institution, nursing home and/or participating unit. In the case that an institution participated in/was involved with multiple affiliated nursing homes and/or units, we examined whether the professionals (e.g. nurse, physician or psychologist) were involved in several/various nursing homes and/or units within the institution, to avoid contamination by professionals. If there was a risk of contamination by professionals, the different affiliated nursing homes and/or units were randomised as 'one': otherwise as 'separate clusters'.

Blinding, observation and performance bias

Implementation of an intervention in a nursing home unit, and subsequent measurement of its effects, means involving healthcare staff in the assessments; these are the people who provide round-the-clock care and know the residents best. Although the residents may have been unaware of being included in the intervention or control condition, and the trained research assistants who collected the outcome measurements were also blinded for the condition, the nurses on whose observations the outcome measurements were based, were not blinded. Therefore, the possibility of (observation) bias (or a Hawthorn effect) cannot be ruled out. Another item to take into account is possible performance bias, since the nurses were the persons performing most of the interventions. However, to minimise these types of bias, an effort was made to evenly divide the attention between the control and intervention condition i.e. in both conditions, physicians received identical training regarding the (evidence-based) treatment of pain and challenging behaviour, the number of site visits were equally distributed, and both conditions received a manual on pain and challenging behaviour. Importantly, however, the manual specifically developed for the control condition (and the training for the healthcare professionals) did not include the stepwise approach for the assessment and treatment of pain and challenging behaviour.

Construct validity: outcome measures i.e. assessment of pain

A particular challenge in the care of patients with dementia is the presence of *pain*. The assessment of pain is a prerequisite for appropriate pain management. In the STA OP! trial we used validated pain observational scales (e.g. the PACSLAC-D and the MDS-RAI pain scale) with good psychometric properties and used more than one outcome measure for each (primary) construct of interest (i.e. behaviour and pain).

Although the outcome measures used for pain are valid, responsiveness is not yet extensively studied. In order to provide effective non-pharmacological or pharmacological treatment, it is essential to identify when a treatment response is present. To facilitate this, there is an urgent need for a pain assessment instrument that can detect changes in pain intensity after an intervention or treatment. Also, it is important that final evaluation of psychometric qualities of a scale considers the criterion of responsiveness against the criterion of reliability. In people with advanced dementia, subtle changes of behaviour are best seen through observation and, as a result, observation of pain (i.e. the PACSLAC-D), or *recollection of behaviour* that may indicate pain, seems to be superior and more acceptable to nurses than estimating or 'guessing' pain (i.e. the MDS-RAI pain scale).[24] Furthermore, in ***Chapter 5*** we show that a reduction of pain was established not by the *'identification or awareness of pain'* by the staff, but mainly by the 'identification of behavioural problems' (see also Table 1 in Chapter 5); therefore, we concluded that the behavioural cues for pain in dementia are essential for better

pain management, and that pain management (and pain assessment in dementia) requires a multidimensional approach, including behavioural observation.[25,26]

Reflections on the findings and implementation of STA OP!

Generalisation of the findings

Considering that the STA OP! study included residents with advanced dementia characterised by a Global Deterioration Scale score of 5, 6 or 7, and complex behavioural challenges or pain, we can assume that this population is largely similar to the nursing home population admitted nowadays, i.e. residents with severe and complex health problems. Therefore, we believe that the findings as described in this thesis are generalisable to the current nursing home setting in the Netherlands.

STI vs. STA OP!

Transfer of the STI (developed and implemented in the USA) to the Dutch version STA OP! required several adaptations, due to differences in the healthcare systems. Besides the similarities between the original STI and the Dutch version (e.g. the stepwise approach and basically the same content in each step) there are also some differences. For instance, the educational background of physicians and nursing staff differ substantially between the Netherlands and USA, as does the composition of a multidisciplinary team in a nursing home.

In the Netherlands, the educational program to become a certified nurse assistant/ nurse assistant takes 2-3 years.[27] In contrast, in the USA, a minimum of 75 hours of initial training is required to become a certified nurse assistant. In addition, Dutch nursing homes employ specialised 'elderly care physicians', with an officially recognised 3-year training for working with complex problems of older people in long-term care[28], to provide and coordinate medical care[29-31] rather than primary care physicians, nurse practitioners or physician assistants. Furthermore, most nursing homes in the Netherlands also employ additional healthcare professionals, e.g. psychologists, physiotherapists and occupational therapists who, together with the nursing staff, form the multidisciplinary care team.[16,31-33] Although there are some differences at the educational and organisational level between the original STI and STA OP!, the results of the STA OP! are in accordance with those of the STI.[34] Therefore, we believe that our findings are generalisable to other long-term care settings, other than the USA.

Fidelity of implementation at the level of residents

Although (beforehand) we expected to assess and treat all eligible residents simultaneously, the limited time available to the nursing staff was a major barrier to applying the protocol to all residents at the same time. Consequently, the intervention was performed in only 58 of the 148 eligible residents, i.e. in only 39.2%.[35] For training and

educational purposes, during the first meeting, the staff selected a sample of residents to start the protocol. This raises questions about the fidelity of the implementation, and the knowledge, time and resources required for implementing such a complex, multicomponent intervention in an RCT. However, despite this disappointing level of fidelity, and the fact that staff were expected to assess behaviour, pain, environmental stimuli, and the physical and psychosocial unmet needs of almost all residents on the unit in a relatively short period of time, it was possible to successfully translate and integrate a tailored intervention into the daily routine and workload of the nursing team. Furthermore, results from the cluster RCT show significant and relevant reductions on both the group and individual level.[36,37] Therefore, it is questionable whether it is necessary to treat all residents in order to observe effects of the intervention.

Selection of residents

One explanation for achieving significant results in this study might be related to the *selection procedure*. In the first training session, the participating professionals selected eligible residents with the most notable challenging behaviours; these residents were the first to be treated with STA OP! Exploratory analyses of residents in the intervention condition (data not published) indicate that, at baseline, these selected residents had significantly more challenging behaviours and also more pain (however, the difference was not significant); this selection may have altered the dynamics on a unit. In addition, residents who were eligible for treatment at baseline, but were not treated at all or were treated in a later phase, had less notable behaviours after assessment and treatment of their fellow residents.

Education and interdisciplinary learning

Another explanation for the positive significant effects might be related to the form of the education, i.e. the training might be seen as small form of action learning[38-41]; every plenary contact moment was followed by a period of 3 weeks in which the healthcare professionals put the steps into practice and were coached at the workplace. This could have led to a knowledge spill-over (or *spill-over effect*) of the intervention; knowledge itself is a necessary condition for successful utilisation of the intervention. *Training an entire team* (not only key persons) creates a set of skills, aptitudes/competences, insights and circumstances that becomes distributed further than merely among the residents involved in the STA OP!, which is subsequently incorporated into daily care.[42,43] In addition, escalation of problems might have been prevented in an earlier stage, making explicit use of the STA OP! in those residents, no longer necessary. Therefore, we argue that the percentage of assessed and treated residents (39.2%) may underestimate the actual extent of implementation.

Complex intervention research

The STA OP! is an example of a complex intervention, in that it encompasses several interacting components. In addition, there are several dimensions of complexity, i.e. STA OP! permits a some flexibility/tailoring of the intervention to manage pain and challenging behaviour, it has a variety of outcome measures, and different groups and organisational levels are targeted.[44-46] When evaluating a complex intervention, it is important to investigate not only its effects, but also its implementation process. For this, a mixed-methods design is recommended; therefore, in our study, a combination of a cluster RCT (quantitative method) and a process evaluation (mixed qualitative and quantitative methods) was used.[44-46]

Process evaluations, which explore the way in which the intervention is implemented, can provide valuable insight into why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised. A process evaluation performed alongside a cluster RCT can be used to assess the fidelity and quality of implementation, and to identify factors inhibiting and promoting implementation. Even when an intervention is 'perfectly' designed, real-world contextual factors may prevent the intervention from being realised as intended.[45-49]

Although we assessed qualitative data from the very start of the trial, we incorporated the mixed-methods design of our process evaluation during the trial. The evaluation would have been more powerful had the mixed-methods design (more specifically the qualitative part) received more attention. For example, we have only an indication that the steps did not seem useful in acute situations or in the terminal stage. More detailed qualitative data would have helped to reveal underlying mechanisms and/or healthcare professionals' beliefs, and further elucidate this matter. Nevertheless, our process evaluation provides valuable insights into the *implementation process* of the STA OP! (***Chapter 7***).

Implications for clinical practice and policy

Implementation of the STA OP! led to a clinically significant improvement of pain and challenging behaviour in residents with advanced dementia. In addition, it empowered healthcare professionals to better deal with these complex problems. Furthermore, it is promising to see that it is not necessary to assess and treat all the residents in a unit with STA OP! in order to observe the effects of this stepwise and individually tailored intervention. Therefore, we recommend implementation of this intervention in daily practice, including the educational programs for healthcare professionals.

When implementing STA OP! the following items may serve to enhance and facilitate implementation:

At the level of the *organisation*:

- Commitment and support by management, providing stability (i.e. no other innovations/changes at the same time), and a shared motivation on change, are essential elements for proper implementation. If these conditions cannot be met, an effort should be made to create better conditions.

At the level of the *team*:

- Implementation should, preferably, start on units with a motivational leader, i.e. a person who is enthusiastic, respected, open to change, well-acquainted with the content through active involvement in the training, and who can motivate and stimulate professionals in the utilisation and implementation of the intervention. If such a motivational leader is not available within the unit and its nursing team, steps should be taken to find a person within the multidisciplinary care team who is willing/capable to take on this position. Alternatively, starting implementation on a different unit within the nursing home should be considered.
- One should involve/engage the whole multidisciplinary team of healthcare professionals, by facilitating participation in the training (preferably in all the meetings), in order to facilitate interdisciplinary learning, mutual collaboration, cooperation, and communication. Involving and engaging the entire multidisciplinary team creates a joint commitment across the unit and/or nursing home to implement change and to pass learning on to other staff i.e. facilitates interdisciplinary learning and cooperation.[50]
- At the beginning of the training (i.e. the first meeting), create and initiate a core team of healthcare professionals, so that they can act as coach and facilitator during the entire training and implementation period.
- Since the assessment of pain is a prerequisite for appropriate pain management, implement and use valid pain observation instruments in daily practice. When self-report is not possible, it is advised to use the PAIC meta-tool, the PACSLAC, the PAINAD, or the REPOS.

At the level of the *individual/professional*:

- By systematically observing behaviours and using the STA OP! assessment, the expertise of healthcare professionals may be better deployed; moreover, it has additional value in that it can substantiate/confirm use of the selected treatments. Not only does implementation of STA OP! provide healthcare professionals with a useful tool at the individual level but, by systematically observing and assessing behaviours, it enhances residents' individually tailored treatments and/or interventions and generally enhances quality of care.

Future research

The present study examined the effects of implementation of STA OP! in residents with advanced dementia. Although significant and clinically relevant reductions of pain, challenging behaviour and mood were found, there were indications that the steps were not always useful in an acute situation or in the terminal stage.

Another point concerns the subtypes and severity of dementia in relation to the effectiveness of STA OP! There is a need to determine which types of neuropathological changes and cognitive impairments are associated with the different forms of dementia, and how these forms relate to pain assessment and management.

Furthermore, it seems worthwhile to examine whether implementation in settings other than the long-term care setting (e.g. a primary care setting) is as effective when treating challenging behaviour and pain in dementia, and also whether STA OP! could be deployed as a preventive measure (since disabling pain and other symptoms have a major impact on a person's independence and quality of life).[51] In the Netherlands, an increasing number of people with dementia live at home. However, implementation of STA OP! in the home care setting might require new strategies, since other professionals (e.g. general practitioners, community nurses and case managers) are often involved in the care for home-dwelling persons with dementia. Interdisciplinary cooperation is seen as a facilitating factor for optimal implementation. A dementia case manager (an independent/permanent counsellor for people with dementia and their families, who informs, guides, advises and manages their care) may act as a key figure to facilitate implementation and involve the different disciplines required for optimal implementation of STA OP!

In addition, it seems worthwhile to explore whether implementation of the STA OP! might be valuable for other groups with frequent challenging behaviour, cognitive impairments and limitations in verbal communications, such as individuals with intellectual disabilities or with Huntington's disease.

CONCLUSION

Both *pain* and *challenging behaviour* are highly prevalent in dementia, and the entanglement between the two makes their relationship (as well as their assessment and treatment) complex and difficult for caregivers. This thesis shows that STA OP!, is effective in reducing pain and challenging behaviour in residents with advanced dementia. In addition, implementation of this systematic, stepwise intervention for pain and challenging behaviour enhances the empowerment of healthcare professionals.
Future implementation of the intervention should start on units which have a leader who is enthusiastic, respected, open to change, well-acquainted with the content through active involvement in the training, and can motivate and stimulate healthcare professionals in the utilisation/implementation of the intervention, i.e. a motivational leader. However, specific features of the organisation and the team (e.g. stability, support, and shared focus on change) should also be considered in order to facilitate implementation.

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